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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/812,393	03/05/97	SHERMAN L	313332000100

EXAMINER	
WILSON, M	
ART UNIT	PAPER NUMBER
1633	18

HM12/0408

KATE H MURASHIGE
MORRISON & FOERSTER
2000 PENNSYLVANIA AVE NW
WASHINGTON DC 20006-1888

DATE MAILED: 04/08/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/812,393	Applicant(s) Sherman et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-21 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-21 are pending in the instant application.

Upon reconsideration, the telephonic restriction requirement by Mary Tung discussed with Kate Mirashige on April 30, 1998 is withdrawn. A new restriction is as follows:

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-5, drawn to a method of identifying and isolating nucleic acids encoding T-cell receptors (TCR) specific for tumor associated antigen (TAA) using a transgenic non-human vertebrate, classified in class 800, subclass 4.

   II. Claims 6-19, drawn to nucleic acids and recombinant cells, classified in class 536, subclass 23.1.

   III. Claim 20, drawn to a method of identifying TAAs, classified in class 435, subclass 70.1+.

   IV. Claim 21, drawn to a method of gene therapy, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the

instant case the DNA encoding TCRs specific for TAA in Group II can be identified and isolated using tumor cell lines and T-cells isolated from cancer patients and grown *in vitro*.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups I and III are unrelated because the method of identifying nucleic acids encoding a TCR using a transgenic animal can be used to isolate nucleic acids encoding TCRs while the method of identifying a TAA can be used to classify tumor types. The method of identifying nucleic acids encoding TCRs does not require identification of cell surface antigens such as TAA. The method of identifying cell surface TAAs does not require identification of nucleic acids encoding TCRs. The reagents and protocols required to identify and isolate nucleic acids are materially distinct and separate from methods of determining cell surface markers such as TAAs.

Groups I and IV are unrelated because the method of identifying nucleic acids encoding a TCR using a transgenic animal can be used to study T-cell response to tumor antigens while a method of administering a gene is for therapy. The method of identifying nucleic acids encoding a TCR does not require a method of gene therapy and a method of gene therapy does not require identifying a nucleic acids encoding TCR. The reagents and protocols required for each method are materially distinct and separate.

Groups II and III are unrelated because the nucleic acids and recombinant cells can be used to make protein while the method of identifying TAA can be used to study tumor

immunology. The nucleic acids and recombinant cells do not require identification of TAA and the method of identifying TAAs does not require nucleic acids and recombinant cells. The reagents and protocols required to make nucleic acids and recombinant cells are materially distinct and separate from those used to identify TAA.

Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA can be used to make protein, to make probes or for gene therapy.

Groups III and IV are unrelated because the method of identifying TAA can be used to study tumor biology while administering DNA can be used as a treatment for cancer. The method of identifying TAA does not require gene therapy and gene therapy does not require identification of TAA. The reagents and protocols required to identify TAA are materially distinct and separate from those used for gene therapy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Groups I-IV are not required for each other, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

mcw

April 6, 1999